## In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 23-848V

BARBARA POWERS,

Chief Special Master Corcoran

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: May 8, 2024

Brynna Gang, Kraus Law Group, LLC, Chicago, IL, for Petitioner.

Naseem Kourosh, U.S. Department of Justice, Washington, DC, for respondent.

## FINDINGS OF FACT<sup>1</sup>

On June 7, 2023, Barbara Powers filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine she received in her right shoulder on November 19, 2021. Pet. at 1, ECF No. 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

<sup>&</sup>lt;sup>1</sup> Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find the Tdap vaccine alleged as causal was more likely than not administered in Petitioner's right shoulder, as alleged.

## I. Relevant Procedural History

Shortly after the initiation of this claim, Petitioner submitted her medical records, affidavit, and a statement of completion. ECF Nos. 6, 8. Among her medical records, Petitioner submitted her proof of vaccination – reflecting a computerized entry stating the subject Tdap vaccination was administered in her "left deltoid." Ex. 2 at 55. This case was then activated and assigned to SPU in October 2023. ECF No. 9.

On December 12, 2023, Respondent filed a status report stating that he has "undertaken medical review of this case" and requesting the Court issue a fact ruling regarding the site of vaccine administration. ECF No. 12. In support of his request, Respondent noted that the vaccination record states the subject Tdap vaccination was administered in Petitioner's left arm. *Id.* (citing Ex. 2 at 55). Respondent highlighted that Petitioner's subsequent reporting states she received the vaccination in her right arm. *Id.* (citing Ex. 2 at 40-51; Ex. 1 at 72, 75, 79; Ex. 4 at 15, 21; Ex. 5 at 76). When Respondent inquired with Petitioner regarding this discrepancy, Petitioner reported "she was not able to locate additional documentation of vaccination." *Id.* Thus, Respondent requests that the Court issue a fact ruling resolving the issue of situs. *Id.* Petitioner subsequently submitted two witness affidavits. ECF No. 13. This matter is ripe for resolution.

#### II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in her right arm. 42 C.F.R. § 100.3(a) I.C & II.C. (2017) (Tdap vaccination).

#### III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally

contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at \*19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

## IV. Finding of Fact

The following finding of fact is based on a complete review of the record, including the petition, all medical records, affidavits, and additional evidence filed. Specifically, I highlight the following:

- Ex. 6 ¶¶ 4-6, Petitioner's affidavit, wherein she attests that on November 19, 2021, she tripped and hit her head and left side on a bike rack, thus requiring a tetanus shot. She states that she "received the tetanus shot in [her] right arm. [She] was sitting down and the nurse was standing over [her]." *Id.* ¶ 6. Petitioner recalls a "pretty ridiculous" bunny band aid, that was "high up on [her] shoulder." *Id.* Petitioner notes that she took a bath the night of the subject vaccination and "noticed that [her] right arm seemed shaky." *Id.* ¶ 7. When she awoke from a nap, she "could barely move [her] right arm." *Id.* Petitioner attests that she "remember[s] particularly that when [she] tried to move [her] right arm away from [her] waist it just stayed there . . . frozen." *Id.*
- Ex. 2 at 50, a record of Petitioner's November 21, 2021 visit (two days post vaccination) with the urgent care facility from whom she received the subject Tdap vaccination. Petitioner reported right shoulder stiffness, although the physician's evaluation also noted "[s]houlder left: tenderness" and described the left shoulder as "stiff, but non-tender to palpation[.]" *Id.* at 51. The physician's assessment included "pain of [the] right shoulder joint on movement" and Petitioner was given work restrictions "regarding the right shoulder." *Id.* at 51-52. Petitioner attests that she complained of right shoulder symptoms during this visit. Ex. 6 ¶ 8.
- Ex. 2 at 46, a record from Petitioner's follow-up appointment with the urgent care facility on November 27, 2021, noting that her "[right] shoulder pain began when she got home" on November 19, 2021, following receipt of the Tdap vaccination. A physical examination revealed "severely" limited range of motion ("ROM") in the right shoulder, along with tenderness and swelling. *Id.* at 47. The physician assessed Petitioner with "acute pain of right shoulder" and referred her to physical therapy ("PT") "for [right] shoulder pain." *Id.* at 47-48.
- Ex. 2 at 40, a record from Petitioner's December 4, 2021 urgent care followup visit for ongoing right shoulder pain. Petitioner reiterated her belief that

such pain was due to her Tdap vaccination.<sup>3</sup> *Id.* An examination revealed diminished ROM and tenderness to palpation of the right shoulder. *Id.* at 41. The physician prescribed steroids and recommended PT for her right shoulder pain. *Id.* at 42.

- Ex. 5 at 76, a record from Petitioner's initial PT evaluation on December 9, 2021. Petitioner "present[ed] . . . with [a complaint of] right shoulder pain" with an onset date of November 19, 2021, following "a tetanus shot in the right arm[.]" *Id.* She specifically reported that "the night of the shot she began having severe pain in the right shoulder[,] which persisted for several days." *Id.* Petitioner exhibited decreased ROM and tenderness of the right shoulder upon examination. *Id.* at 77.
- Ex. 1 at 72, Petitioner's January 7, 2022 visit with her primary care physician ("PCP") for "musculoskeletal pain." Petitioner reported right shoulder pain and noted she "was given a tetanus booster in [her] right arm and . . . it has affected her right arm ever since." \*4 Id.
- Ex. 2 at 19, a record from Petitioner's January 24, 2022 visit with a different provider at the urgent care facility where she received the subject vaccination, for ongoing right shoulder pain. The record contains an "impression" that the tetanus vaccination "was documented as being given in the left deltoid and [Petitioner] is reporting injury in [the] right [deltoid]." *Id.* at 20. Petitioner attests that it was during this visit she was told that "the vaccine administrator had recorded that she had given [Petitioner] the vaccine in [her] left arm." Ex. 6 ¶ 22. She contends "[t]his is completely inaccurate" and that she has "always reported that [her] right shoulder pain was from [her] vaccination in that arm." *Id.* Petitioner asserts that the left deltoid entry was a "charting error." *Id.*
- Ex. 4 at 7, a record from Petitioner's orthopedic evaluation on February 23, 2022. The chief complaint was recorded as "I fell and hurt my Right shoulder 11/19/2021." Petitioner stated that following this fall, she received a tetanus shot "which was performed into the right shoulder." *Id.* Petitioner

<sup>&</sup>lt;sup>3</sup> Petitioner maintained this belief at several additional follow-up visits at the urgent care facility for her right shoulder pain. See, e.g., Ex. 2 at 35 (a December 11, 2021 follow-up visit); Ex. 2 at 30 (a December 27, 2021 follow-up visit); Ex. 2 at 24 (a January 10, 2022 follow-up visit); Ex. 2 at 12 (a February 7, 2022 follow-up visit).

<sup>&</sup>lt;sup>4</sup> The same note appears in a note for Petitioner's April 22, 2022 follow-up visit with her PCP. Ex. 1 at 79.

- underwent an examination of the right shoulder and was diagnosed with right rotator cuff syndrome. *Id.* at 8.
- Ex. 4 at 19, a record from Petitioner's June 23, 2022 MRI of the right shoulder – showing moderate supraspinatus and infraspinatus tendinosis, moderate degenerative changes to the acromioclavicular joint, and "mild edema within supraspinatus and infraspinatus muscles with mild to moderate fatty infiltration, suggestive of denervation changes."
- Ex. 4 at 15, a record from Petitioner's July 11, 2022 visit stating Petitioner "ha[d] been having right shoulder pain after a tetanus injection that was administered too high." Petitioner received a steroid injection in the right shoulder to address her right shoulder symptoms. *Id.* at 15-16.
- Ex. 3 at 24, a record from Petitioner's initial visit for her second round of PT on July 26, 2022, noting "right shoulder pain after receiving a tetanus shot on 11/19/22 [sic]." The physician wrote that Petitioner "presented to the clinic with signs and symptoms of right shoulder pain secondary to SIRVA." Id. at 25. Petitioner continued PT for her right shoulder pain for several months throughout 2022. See, e.g., Ex. 5 at 12-16.
- Ex. 7 ¶¶ 5-6, an affidavit from Petitioner's co-worker (Lindsay Binder), attesting that the day after Petitioner's fall and subsequent Tdap vaccination, Ms. Binder observed that Petitioner "couldn't raise her right arm" when reaching for a laptop. Petitioner told Ms. Binder that "she had gotten a tetanus shot . . . the day before and that her right arm was now very painful from her vaccination." *Id.* Ms. Binder notes that they "talked specifically about her vaccination being in her right arm" because she saw a band-aid on that arm. *Id.* ¶ 7. Ms. Binder attests to Petitioner's ongoing right shoulder limitations. *Id.* ¶¶ 8-9.
- Ex. 8 ¶ 6, an affidavit from Petitioner's daughter, Kimberly Powers, noting that Petitioner "told her that she had gotten a tetanus shot in her right arm and that her arm was sore." Ms. Powers "remember[s] seeing [Petitioner's] right arm and [she] could see that the band aid at the vaccination site was kind of silly[.] It was colorful and was obviously a kid's band-aid." *Id.* Ms. Powers describes functional limitations she observed in Petitioner's right arm, including with bathing, eating, and typing as Petitioner is right-hand dominant. *Id.* ¶¶ 6, 9-11.

The above evidence preponderantly supports the conclusion that Petitioner's November 19, 2021 Tdap vaccine was likely administered in her right shoulder, as alleged. The record of Petitioner's November 21, 2021 urgent care follow-up visit noting right shoulder pain and stiffness requiring work modifications for her right shoulder (Ex. 2 at 50-52), is particularly persuasive. This record is from only two days post vaccination and is the most contemporaneous record other than the vaccine administration record itself. While it does also reference left shoulder issues, overall, the thrust of the documents from this visit are consistent with a primarily right-side complaint.

Petitioner's right shoulder administration arguments are further corroborated by Petitioner's November 27, 2021 follow-up visit (six days later) (Ex. 2 at 46), and visits thereafter, wherein Petitioner consistently reports that her right shoulder pain began the night of the subject Tdap vaccination in that arm. And as the above-referenced medical records further establish, when seeking medical treatment on every subsequent occasion, Petitioner consistently reported right shoulder pain attributable to her Tdap vaccination. See, e.g., Ex. 1 at 72; Ex. 2 at 19-20, 40; Ex. 3 at 24; Ex. 4 at 7-8, 15, 19; Ex. 5 at 76.

I acknowledge that the vaccine administration record *itself* memorializes a different site of the administration of Petitioner's Tdap vaccine. Ex. 2 at 55. But the record is an automated, computer-generated, electronic entry. *See id.* It is not unusual for the information regarding situs of vaccination set forth in this kind of document to be incorrect.<sup>5</sup> In many instances, the information regarding situs has been recorded prior to vaccination and is not subsequently corrected, even if the vaccine is then administered in the opposing arm.<sup>6</sup> Thus, although such records are unquestionably the first-generated documents bearing on the issue of site, and merit some weight as a result, they are not *per se* reliable simply because they come first. In fact, I have previously determined that the very nature of vaccination record creation provides some basis for *not* accepting them as the evidence worthy of highest probative weight. *See*, e.g., *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-881V, 2022 WL 2284311, at \*4 (Fed. Cl. Spec. Mstr. May 13, 2022). More so, I routinely give greater weight to vaccination records that are handwritten –

<sup>&</sup>lt;sup>5</sup> See, e.g., Arnold v. Sec'y of Health & Hum. Servs., No. 20-1038V 2021 WL 2908519, at \*4 (Fed. CL. Spec. Mstr. June 9, 2021); Syed v. Sec'y of Health & Hum. Servs., No. 19-1364V, 2021 WL 2229829, at \*4-5 (Fed. Cl. Spec. Mstr. Apr. 28, 2021); Ruddy v. Sec'y of Health & Hum. Servs., No 19-1998V, 2021 WL 1291777, at \*5 (Fed. Cl. Spec. Mstr. Mar. 5, 2021); Desai v. Sec'y of Health & Hum. Servs., No 14-0811V, 2020 WL 4919777, at \*14 (Fed. Cl. Spec. Mstr. July 30, 2020); Rodgers v. Sec'y of Health & Hum. Servs., No. 18-0559V, 2020 WL 1870268, at \*5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); Stoliker v. Sec'y of Health & Hum. Servs., No. 17-0990V, 2018 WL 6718629, at \*4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

<sup>&</sup>lt;sup>6</sup> In a recent ruling by another special master, the pharmacist who had administered the relevant vaccination actually testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, based upon the assumption that most vaccinees are right-handed. *Mezzacapo v. Sec'y of Health & Hum. Servs.*, No. 18-1977V, 2021 WL 1940435, at \*4 (Fed. Cl. Spec. Mstr. Apr. 19, 2021).

meaning those that require specific action on the part of the vaccine administrator, as opposed to those that are automatically generated by a computerized system. *See,* e.g., *Rizvi,* 2022 WL 2284311, at \*5; *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2020 WL 1870268, at \*5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020).

The vaccine administration form at issue in this case is an automated entry in a computerized system. It is the only evidence in this case that contradicts Petitioner's assertion and supports a finding of left arm situs. Given the general unreliability of an automated vaccination record, and when weighed against Petitioner's clear, consistent, and close-in-time reports of right shoulder pain following her receipt of a Tdap vaccine in that arm, I find by a preponderance of the evidence that Petitioner received her November 19, 2021 Tdap vaccine in her right arm. To rule otherwise, the overall record would need to contain more instances in which the counter situs was suggested or supported.

## V. Scheduling Order

Respondent shall file, by no later than <u>Wednesday</u>, <u>May 22, 2024</u>, a status report concerning how he intends to proceed. At a minimum, the status report shall indicate whether he is willing to engage in tentative discussions regarding settlement or proffer or is opposed to negotiating at this time. In the event Respondent wishes to file a Rule 4(c) report, he may propose a date for filing it, but shall indicate his position on entering into negotiations regardless of whether he wishes to file a Rule 4(c) report.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master